UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

IN RE THALOMID AND REVLIMID ANTITRUST LITIGATION	Civil Action No. 2:14-cv-6997-MCA-MAH Honorable Madeline Cox Arleo, U.S.D.J. (Document Filed Electronically)

CELGENE CORPORATION'S MEMORANDUM IN OPPOSITION TO CLASS PLAINTIFFS' MOTION FOR CLASS CERTIFICATION

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I. INTRODUCTION

Class certification in indirect purchaser antitrust cases is a complex endeavor. Plaintiffs seeking to represent a class under Federal Rule of Civil Procedure 23(b)(3) have the burden to show, among other things, that they can feasibly identify the members of the class and that common issues predominate over individual issues. The court's review of these requirements is rigorous, and often leads to denial of certification when individualized inquiry would be necessary to determine the impact on class members of the defendants' allegedly anticompetitive conduct. In particular, courts have rejected attempts to certify classes of indirect purchasers of brand name pharmaceutical products allegedly injured by an absence of generic competition, citing the complex and multi-layered nature of the marketplace for medicines. Class members include patients, insurers, health plan sponsors ("Sponsors"), and pharmacy benefit managers ("PBMs"), any of whom may—or may not—bear a portion of any alleged overcharge, depending on the particular details of their contractual relationships in the pharmaceutical distribution chain. Determining who is in the class, and who (if anyone) suffered injury, requires an individualized inquiry unsuited to class-wide proof.

Plaintiffs do not grapple with these complexities. Instead, Plaintiffs devote much of their brief to an attack on Celgene's conduct, which (while inaccurate, as Celgene will show when it is time to litigate the merits) is beside the point for class certification. When Plaintiffs seek to articulate how they will identify class members and prove damages on a class-wide basis, as Rule 23 requires, their "method" is a Potemkin village: a façade that, upon closer examination, does not account for the fundamental differences among market participants who could qualify as class members. Certification should be denied for four central reasons:

First, Plaintiffs cannot satisfy their burden of ascertainability, which requires them to explain at the class certification stage how they will identify membership in the classes without

burdensome individualized inquiry. Whether a purchaser of Thalomid® or Revlimid® bears some or all of the purchase price for these drugs, and thus is a class member, depends on the terms of its individual contractual relationships. For consumers, membership will depend on the patient's health plan, including whether it includes a flat copayment or an annual out-of-pocket maximum. For Sponsors, membership will depend on the Sponsor's arrangement with its PBM, including the discount and rebate terms, and any insurance the Sponsor may have. For PBMs, membership will depend on the PBM's arrangements with pharmacies, Sponsors and/or insurers, as well as drug manufacturers. And so on. Plaintiffs offer no method short of a detailed individualized examination to answer these questions. They also offer no workable method to show which payors have claims under the laws of one of the thirteen relevant states or the District of Columbia, as opposed to a jurisdiction outside the class definitions.

Second, Plaintiffs cannot show that common issues predominate over individual issues. Their predominance burden includes distinguishing injured from uninjured class members and offering a method of proving damages on a class-wide basis. Given the differences among class members' payment relationships, this is a daunting task, which Plaintiffs do not confront; their proposed method is merely to calculate an across-the-board "average overcharge." Plaintiffs also had the burden to explain how they would account for the significant differences among state laws in the fourteen jurisdictions whose laws they invoke, but their answer is to claim that those differences do not exist.

Third, Plaintiffs' only individual consumer class representative, Mr. Mitchell, does not satisfy Rule 23(a)'s requirements of typicality or adequacy because he lacks standing to sue.

Fourth, Plaintiffs' proposed Injunction Class should not be certified under Rule 23(b)(2) because the primary remedy Plaintiffs seek is money damages.

For all of these reasons, Plaintiffs' Motion to certify the putative classes should be denied.

II. COUNTER-STATEMENT OF THE FACTS

Plaintiffs devote nearly half of their brief to a "Statement of Facts" that is utterly immaterial to their motion for class certification. Mem. at 3–24.[1] Lest there be any doubt, Celgene will vigorously dispute that it engaged in any anticompetitive conduct or that lawful generic entry could have occurred during the putative class periods in the absence of this alleged conduct. Indeed, many of the so-called "facts" in Plaintiffs' statement are demonstrably false. But even if Celgene had done everything it is accused of, that would not cure Plaintiffs' failure to satisfy their burden to meet the requirements of Rule 23, which has nothing to do with how sinister a plaintiff may attempt to portray a defendant's conduct.

The facts that actually matter to this Motion are those that bear on whether Plaintiffs have met their burden of showing that their proposed classes are ascertainable, whether Plaintiffs can prove injury-in-fact or damages on a class-wide basis under the laws of thirteen separate states[2] and the District of Columbia ("Damages Jurisdictions"), and whether David Mitchell is an adequate class representative. This Brief, in contrast to Plaintiffs', will focus on *those* facts.

A. Plaintiffs' Class Certification Theories.

Plaintiffs seek to certify three classes of indirect purchasers of Celgene's brand-name medicines, Thalomid and Revlimid: (1) an Antitrust/Consumer Protection Damages Class based

[1] Citations to "Mem." and "Mem. App." refer to Plaintiffs' memorandum in support of their motion for class certification and their appendices, respectively. Citations to "App." refer to the appendices to this memorandum. Citations to "Ex." refer to the exhibits attached to the Declaration of John E. Schmidtlein, filed herewith.

[2] The thirteen states are California, Florida, Kansas, Maine, Massachusetts, Michigan, Nebraska, New York, North Carolina, Oregon, Pennsylvania, Rhode Island, and Tennessee. Mem. at 1.

on the laws of the Damages Jurisdictions; (2) an Unjust Enrichment Damages Class based on the laws of the Damages Jurisdictions; and (3) an Injunction Class based on federal antitrust law.[3] Mem. at 1, 49. Plaintiffs claim that Celgene took actions to prevent generic competition for these medicines, and that as a result, members of the three putative classes paid more for Thalomid and Revlimid than they would have paid for a generic equivalent.

Plaintiffs define their two putative Damages Classes as all persons and entities who purchased and/or paid for some or all of the purchase price for Thalomid after November 6, 2010, or Revlimid after January 29, 2011, in the Damages Jurisdictions. Mem. at 1. The Injunction Class includes these same persons and entities who paid for these drugs anywhere in the United States. All three classes exclude, among others, direct purchasers and/or resellers of these drugs, fully insured health plans, single flat copay consumers, and government entities. *Id.* at 1 & n.1.

B. Structure of the Pharmaceutical Marketplace.

Plaintiffs' request to certify classes of persons or entities "who purchased and/or paid for some or all of the purchase price" for Thalomid or Revlimid in certain states, Mem. at 1, requires an understanding of who these purchasers are and the terms of their purchases. The pharmaceutical marketplace is complicated, featuring multiple layers of payments and reimbursements, based on separate but often interdependent contractual relationships. Plaintiffs ignore these complexities in their brief, but they could not be more fundamental to the Rule 23 inquiry. They determine whether class members can be identified, whether injury can be

[3] Plaintiffs' operative Complaint sets forth claims for violations of the laws of 35 additional states and the United States territories. Dkt. No. 143 ("Am. Compl.") ¶¶ 261, 300, 306, 310, 322. For the reasons set forth in Celgene's Motion for Judgment on the Pleadings, filed concurrently with this Opposition, Plaintiffs lack standing to sue under those jurisdictions' laws, and those claims should be dismissed.

established through class-wide proof, and whether damages may reliably be estimated on a class-wide basis.

The simplest type of transaction is when an uninsured consumer purchases a prescription from his pharmacy, either at a retail store or by mail. In that scenario, the consumer will pay the pharmacy for the medication at the price the pharmacy sets, and the pharmacy will pay the drug manufacturer or the wholesaler. Ex. 1 (Hughes Rep. ¶ 15).

That relatively straightforward scenario is uncommon. Instead, most prescription drug purchases are made by consumers with health insurance. Ex. 1 (Hughes Rep. ¶ 16). In those scenarios, the flow of payments is far more complex and multi-layered. When (1) an insured patient purchases a medicine from (2) a pharmacy, the patient may pay a portion of the cost, but the remainder of the charge is typically paid in the first instance by (3) a PBM on behalf of (4) the Sponsor, which is an employer, a union, or other employee organization that offers the consumer's health insurance plan. *Id.* ¶¶ 16–17. PBMs typically have separate contracts with pharmacies and Sponsors; those contracts determine the prices a PBM will pay to the pharmacy for the medicines, and the (often different) prices the Sponsor will reimburse to the PBM for the same medicines. *Id.* ¶¶ 17, 21, 35. The amount the patient herself pays to the pharmacy is determined by still another separate contract—the patient's insurance agreement with the Sponsor. *Id.* ¶¶ 16, 39.

Further complicating the payment picture are other parties that may be responsible for some or all of the costs of a prescription: (5) Instead of contracting directly with PBMs, Sponsors may instead contract with commercial health insurers to manage both the medical and the pharmacy benefits; and the commercial health insurer may then outsource the pharmacy benefit management to a PBM. Ex. 1 (Hughes Rep. ¶ 16). Commercial health insurers may also

provide benefits directly to consumers when consumers purchase such health insurance separately from their employer or union. (6) Drug manufacturers often provide rebates to the PBM or the health insurer, which affects the amount each potential class member pays for the medication. *Id.* ¶¶ 21, 36. (7) [redacted] For any given prescription, each such entity may—or may not—pay a portion of the purchase price.

These interlocking relationships have enormous consequences for the amounts potential class members paid for Thalomid and Revlimid, and for the pivotal question of whether those payments would have been lower if generic versions of the medicines had been on the market.

1. Payments by Consumers.

Consumers with prescription drug coverage pay different prices for the same medicines, depending on the details of their insurance plans. Ex. 1 (Hughes Rep. ¶ 39). [redacted]

Consumers with prescription drug coverage pay a fixed-dollar amount ("copay") or a percentage of the cost ("coinsurance") on each prescription. Ex. 1 (Hughes Rep. ¶ 40). The copay and coinsurance amounts vary by health plan. *Id.* ¶¶ 39–40. Some customers pay a "single flat copay": a fixed amount per prescription regardless of whether it is a brand or a generic. Single flat copay consumers are excluded from Plaintiffs' proposed classes because they suffered no injury from the absence of a generic. *See* Mem. at 1 & n.1.

Many health plans have out-of-pocket ("OOP") maximums for prescription drug benefits or medical services generally, meaning that once a consumer has paid a certain amount during

the plan year, the consumer will not have to pay any of the cost of future prescriptions. Ex. 1 (Hughes Rep. ¶ 41). Those OOP maximums vary depending on the plan, and some plans measure OOP maximums on a family, as opposed to individual, basis. *Id.* [redacted]

For Medicare Part D beneficiaries, a significant portion of Thalomid and Revlimid users, the payments vary depending on the plan the consumer joins and the consumer's spending throughout the year. Ex. 1 (Hughes Rep. ¶ 42). As the consumer spends certain target amounts, the cost sharing among the consumer, the government, the health plan, and the drug manufacturer also varies. *Id*. In the "catastrophic coverage" stage, the government will pay 80 percent of future costs. *Id*. ¶ 43. The government's role is even greater if the consumer is eligible for a Low Income Subsidy ("LIS"), in which case the government will also pay most of the consumer's premium and cost sharing. *Id*. ¶¶ 33, 44.

2. Payments by Sponsors, PBMs, and Insurers.

Sponsors may, or may not, pay some or all of the cost of the health benefits they offer to their members or employees. This depends on whether the Sponsors provide fully-insured or self-insured health plans and on their contractual relationships with other entities in the marketplace, such as PBMs and stop-loss insurers. Ex. 1 (Hughes Rep. ¶¶ 20–22).

Fully Insured Plans. Sponsors often obtain commercial insurance covering members' prescriptions. A Sponsor with a "fully insured" plan will not bear any of the net cost of a prescription; instead, the Sponsor will pay an annual premium to a health insurance company, and that insurer will cover all of the prescription drug costs. Ex. 1 (Hughes Rep. ¶ 20). Plaintiffs' proposed classes exclude entities with fully-insured plans. *See* Mem. at 1 & n.1.

Self-Insured Plans and PBMs. A plan that is not "fully" insured by a third-party insurer is "self-insured" by the Sponsor. Some such Sponsors manage their own prescription benefits, paying the pharmacy directly for any amounts not paid by the consumer. Ex. 1 (Hughes Rep. ¶ 21). Most Sponsors contract with a PBM to manage the plan's pharmacy benefits. *Id*. In that scenario, the PBM pays the pharmacy and obtains some amount of reimbursement from the Sponsor. *Id.*

The amount the PBM pays to the pharmacy varies depending on the PBM's contractual relationship with the pharmacy. Ex. 1 (Hughes Rep. ¶¶ 21, 35). For example, a pharmacy may offer a PBM certain discounts off the list price of a drug in exchange for being the health plan's "preferred" pharmacy and thus receiving additional business. *Id*. ¶ 35.

The amount the Sponsor reimburses to the PBM for any particular prescription also varies depending on *their* contractual relationship. Ex. 1 (Hughes Rep. ¶¶ 21, 35). [redacted] Other PBMs offer Sponsors guaranteed discounts from retail prices, where the amount of the discount may depend on multiple factors such as whether the prescription was a brand, a generic, or a specialty drug; whether it was obtained in a retail pharmacy or through the mail; and how many units were purchased. *Id*. ¶¶ 37, 73.

[redacted]

[redacted] In those instances, the PBM is not injured by the unavailability of a generic. [redacted] In that instance, the Sponsor would not be injured by the unavailability of a generic.

Self-Insured Plans and Stop-Loss Insurance. [redacted] They obtain insurance known as "stop-loss" or "excess" insurance covering health benefit costs once they reach a certain threshold amount. *Id.* ¶ 22. The details of any particular stop-loss insurance policy will vary, but such policies typically provide that when a Sponsor incurs costs in excess of a set limit, or "deductible," the third party insurer will cover the remaining costs. Like an individual customer with an OOP maximum, therefore, a Sponsor with stop-loss coverage is not injured if it would have hit its deductible regardless of whether its members were purchasing brand or generic Thalomid or Revlimid. *Id.* ¶¶ 22, 62.

Plaintiffs' proposed classes would appear to include all of the types of consumers and entities described above: uninsured consumers; insured consumers; insured consumers with OOP maximums; PBMs; Sponsors; commercial health insurers offering prescription drug coverage; and third-party insurers offering stop-loss insurance to Sponsors.

[redacted]

III. ARGUMENT

Plaintiffs fail to meet multiple critical requirements for certifying a class under Rule 23. Under established Third Circuit precedent, these shortcomings preclude certification of all of Plaintiffs' putative classes.

A. PLAINTIFFS' PROPOSED DAMAGES CLASSES ARE NOT ASCERTAINABLE

To satisfy the requirement of "ascertainability," Plaintiffs must show that they can identify the members of their proposed classes through an objective and administrable method. Although Plaintiffs recite the general ascertainability standards, they ignore entirely two decisions from courts in this Circuit denying certification of Rule 23(b)(3) damages classes in virtually indistinguishable circumstances: *Vista Healthplan, Inc. v. Cephalon, Inc.*, No. 2:06-cv-1833, 2015 WL 3623005, at *11–13 (E.D. Pa. June 10, 2015), *reconsideration denied*, 2015 WL 4737288 (E.D. Pa. Aug. 4, 2015), and *In re Wellbutrin XL Antitrust Litigation*, 308 F.R.D. 134, 149–50 (E.D. Pa. 2015). Those cases—and Plaintiffs' own documents and testimony—demonstrate that Plaintiffs have failed to set forth a methodology for ascertaining class members, and excluding non-class members, as required by Third Circuit law. Plaintiffs' efforts to certify the Antitrust/Consumer Protection and Unjust Enrichment Damages Classes should be denied on ascertainability grounds.

1. Legal Background.

Ascertainability is "an essential prerequisite of a class action." *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 592 (3d Cir. 2012). Plaintiffs are required to show, "by a preponderance of the evidence, that the class is 'currently and readily ascertainable based on objective criteria,' and a trial court must undertake a rigorous analysis of the evidence to determine if the standard is met." *Carrera v. Bayer Corp.*, 727 F.3d 300, 306 (3d Cir. 2013)

(quoting *Marcus*, 687 F.3d at 593). "The proposed method for ascertaining a class must be supported by evidence—assurances of the ability to ascertain a class in the future are insufficient." *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 124, 135 (E.D. Pa. 2015); *accord Byrd v. Aaron's Inc.*, 784 F.3d 154, 163–64 (3d Cir. 2015), *as amended* (Apr. 28, 2015). "Nor may a party 'merely propose a method of ascertaining a class without any evidentiary support that the method will be successful.'" *Byrd*, 784 F.3d at 164 (quoting *Carrera*, 727 F.3d at 306). "Ascertainability mandates a rigorous approach at the outset because of the key roles it plays as part of a Rule 23(b)(3) class action lawsuit." *Carrera*, 727 F.3d at 307. In particular, it "'eliminates serious administrative burdens'"; "'allows for the best notice practicable, and thereby protects absent class members; and protects defendants by clearly identifying the individuals to be bound by the final judgment.'" *Hayes v. Wal-Mart Stores, Inc.*, 725 F.3d 349, 355 (3d Cir. 2013) (quoting *Marcus*, 687 F.3d at 593).

The ascertainability inquiry is two-fold: (1) "the class must be defined with reference to objective criteria"; and (2) "there must be a reliable and administratively feasible mechanism for determining whether putative class members fall within the class definition." *Hayes*, 725 F.3d at 355. "If class members are impossible to identify without extensive and individualized fact-finding or 'mini-trials,' then a class action is inappropriate," *Marcus*, 687 F.3d at 593, because the "significant benefits of a class action are lost," *Carrera*, 727 F.3d at 307. Plaintiffs' proposed method for identifying class members therefore must be "a manageable process that does not require much, if any individual factual inquiry." *Id.* at 307–08.

Two district courts in the Third Circuit recently have addressed the ascertainability requirement in substantially analogous cases where the plaintiffs sought to represent classes of indirect pharmaceutical purchasers allegedly injured by brand manufacturers who thwarted

generic competition. In both cases, the courts found certification improper because the plaintiffs had not shown that the proposed classes were ascertainable. Because Plaintiffs' Motion suffers from identical ascertainability problems, the same result should follow.

In *Vista Healthplan, Inc. v. Cephalon, Inc.*, the plaintiffs alleged that the defendants delayed the market entry of generic Provigil by enforcing a fraudulently obtained patent and entering into anticompetitive patent litigation settlements. 2015 WL 3623005, at *1. The plaintiffs sought to certify a class of "persons or entities . . . who purchased Provigil and/or its generic equivalent" in certain states, but (as here) excluding, among other groups, "insured individuals covered by plans imposing a flat dollar copay that was the same dollar amount for generic as for brand purchases" and "fully insured health plans." *Id.* at *4.

The court concluded that, in light of "the complex nature of the pharmaceutical and insurance industries," there was no "administratively feasible approach that would allow Plaintiffs to distinguish class members." *Vista Healthplan*, 2015 WL 3623005, at *11–12. The court emphasized that identifying class members would require "'consideration of the individual contractual relationships underlying each transaction. . . . [U]ntil proceeding through each transaction and resolving factual disputes . . . the Court cannot say who is a member of the class, that is, who has paid or reimbursed a portion of the purchase price.'" *Id.* at *12 (brackets in original) (quoting *In re Skelaxin (Metaxalone) Antitrust Litig.*, 299 F.R.D. 555, 569, 571 (E.D. Tenn. 2014)). The court also rejected the plaintiffs' assertions that these issues could wait until the damages allocation phase: Under binding Third Circuit law, "[p]laintiffs must, *at the time of class certification*, present a methodology to identify class members, and prove by a preponderance of the evidence that such methodology will be effective and will not require extensive individualized inquiry and mini-trials." *Vista Healthplan*, 2015 WL 3623005, at *10.

In *Wellbutrin XL Antitrust Litigation*, the plaintiffs alleged that the defendants' anticompetitive settlements of infringement lawsuits had delayed the entry of generic Wellbutrin. 308 F.R.D. at 137. Prior to the Third Circuit's decision in *Marcus*, the district court had certified a class of "persons or entities who purchased an AB-rated generic bioequivalent of Wellbutrin XL." *Id.* at 138. The class definition (as here) excluded "flat co-payers." *Id.* The defendants later moved to decertify the class after the Third Circuit's decisions in *Marcus*, *Hayes*, *Carrera*, and *Byrd*, and the district court granted the motion.

The court held that the plaintiffs had "not shown by a preponderance of the evidence that there is a reliable and administratively feasible mechanism for determining which PBMs and individual consumers are members of the class." *Wellbutrin*, 308 F.R.D. at 149–50. The court rejected the plaintiffs' "repeated assurances . . . that there are extensive purchase records in the pharmaceutical industry that could be used to ascertain" class members, noting that plaintiffs had failed to obtain such records through subpoenas. *Id.* at 150. And the court emphasized that neither of the plaintiffs' experts had in fact "examined or analyzed the[] pharmaceutical records [that were available] . . . to show that they could be used to ascertain PBMs and individual consumers." *Id.* Even assuming *arguendo* that the plaintiffs could obtain additional records, the court found the class still was not ascertainable because "[t]here are thousands of PBMs and retail pharmacies" and the plaintiffs had "not produced any evidence showing that it could synthesize records from these disparate entities and use them to ascertain PBMs and individual consumers in a reliable and administratively feasible manner." *Id.*

Ignoring these closely analogous cases from district courts within the Third Circuit, Plaintiffs instead cite to a case from the Ninth Circuit. Mem. at 32 (citing *In re Lidoderm Antitrust Litig.*, No. 14-md-02521, 2017 WL 679367, at *25 (N.D. Cal. Feb. 21, 2017)).

Plaintiffs' reliance on *Lidoderm* is misplaced, not least because *the Ninth Circuit does not recognize ascertainability as a requirement under Rule 23*. *See Lidoderm*, 2017 WL 679367, at *25 ("As the Ninth Circuit recently explained, ascertainability . . . is not a requirement under Rule 23." (citing *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1125 (9th Cir.), *cert. denied*, 138 S. Ct. 313 (2017)). Third Circuit law is otherwise.

2. Plaintiffs Have Not Shown, and Cannot Show, that the Damages Classes Are Ascertainable.

Plaintiffs have taken no steps to address the ascertainability flaws that were dispositive in *Vista Healthplan* and *Wellbutrin*. Instead, Plaintiffs offer the same arguments that those courts rejected, promising that documents will show the purported purchases by putative class members. Like the plaintiffs in those cases, Plaintiffs had the burden to prove this assertion at the class certification stage, and they have not. In fact, the discovery record in this case shows just the opposite: the scant documents Plaintiffs append as exhibits do not provide anywhere near sufficient information to identify (a) what entities or consumers are members of the classes; (b) the flat copay consumers and fully insured health plans that are excluded; or even (c) which entities or consumers have claims in the fourteen Damages Jurisdictions—much less that such documents exist industry-wide to prove membership in the putative classes. And Plaintiffs ignore entirely the role of PBMs and stop-loss insurers—two substantial categories of potential class members for which Plaintiffs have no methodology at all.

a. Plaintiffs' class definitions require an analysis of "net" payments in order to ascertain class members.

Plaintiffs define their Damages Classes as those persons and entities who "purchased and/or paid for some or all of the purchase price" in the Damages Jurisdictions, excluding those who purchased directly from Celgene. Mem. at 1 & n.1. But Plaintiffs do not explain what qualifies, under their proposed classes, as "purchas[ing]" or "pay[ing] for" part of the price, and

they ignore a critical link in the prescription reimbursement chain: PBMs. Plaintiffs assert that "[t]he Classes consist of patients, health benefit plans, and insurers"; they do not mention other entities. Mem. at 32. [redacted]

Plaintiffs thus apparently mean to distinguish between those entities that bear payment risk on the transaction (who are within the proposed class) and pass-through intermediaries (who purportedly are not). [redacted] If that is the distinction Plaintiffs mean to draw, then their ascertainability burden is to articulate a method for identifying persons or entities who bore a portion of the net purchase price after accounting for all payments by other entities.[5]

[redacted] As explained above, some PBMs operate as pass-through entities, but others bear some portion of the cost of medicine purchases under the terms of their contracts with Sponsors. Plaintiffs therefore were obliged to propose a method to distinguish between those PBMs that bear payment risk, and so are in the class, and those that do not, and so are out. The court in *Wellbutrin* enforced this very requirement, rejecting the plaintiffs' argument that PBMs were not potential class members. 308 F.R.D. at 148 (finding plaintiffs must "show[] that [they]

[5] If Plaintiffs intend to include pass-through entities in their class definitions, then the classes include even more entities that suffered no injury from the alleged unlawful conduct, which would further exacerbate their ascertainability and predominance problems.

can ascertain which PBMs, if any, are members of the class").

b. Plaintiffs' proposed "method" for ascertaining purchasers who are class members is not administratively feasible.

Plaintiffs pay scant attention to their method for identifying class members. *See* Mem. at 33–34. In effect, their proposal consists of "repeated assurances . . . that there are extensive purchase records in the pharmaceutical industry." *Wellbutrin*, 308 F.R.D. at 150. The courts in *Wellbutrin* and *Vista Healthplan* rejected similar proposals in light of the complexity of the transactions and relationships in that industry.

Plaintiffs' proposal does not even compare to what the (failing) plaintiffs in *Wellbutrin* and *Vista Healthplan* offered: those plaintiffs at least offered expert testimony on ascertainability in addition to the same pharmaceutical records Plaintiffs cite here. In *Wellbutrin*, for example, the plaintiffs submitted data from an insurance carrier class representative, pharmaceutical purchase records from two health and welfare plans, and a "proposed trial plan," and retained two experts who opined that class members "can be ascertained using pharmacy reports, receipts, and prescription bottles." 308 F.R.D. at 142–43. The court concluded that the plaintiffs had "put forward scant evidence to support [their] claim," and denied class certification. *Id.* at 150. The problem was that the plaintiffs did not show that the documentation would actually allow them to identify the purchasers who were members of the class short of conducting an individualized inquiry. *Id.* That problem is even more glaring here:

Consumers. Plaintiffs propose four potential sources for identifying consumer class members: (1) purchase receipts; (2) pharmacy prescription records; (3) insurer prescription records; and (4) Celgene's REMS database. Plaintiffs assert, without any evidence, that "patients are more likely to retain receipts for Thalomid and Revlimid than for ordinary consumer purchases." Mem. at 34. Discovery has undermined this assertion. [redacted]

[redacted]

Plaintiffs also assert that patients can prove their purchases by obtaining records from their pharmacies or insurers. But Plaintiffs had the burden to substantiate their claim with actual records, and they have not done so: they produced no such records for Mr. Mitchell for the majority of the time he was taking Revlimid, and woefully insufficient samples of records that supposedly would identify other class members.[6]

Plaintiffs finally say that Celgene's REMS data would contain the "last name, date of birth, partial social security number, prescribing physician, and dispensing pharmacy for each patient, and the name and address of every pharmacy dispensing either drug." Mem. at 33. None of that matters here. Plaintiffs do not claim (as they must) that the REMS data would show how much of the purchase price, if any, was paid by the patient, as opposed to her insurer or Sponsor.

Plan Sponsors and Commercial Insurers. Plaintiffs propose two methods for identifying Sponsor and commercial insurer class members: (1) member or insurer claims data; or (2) pharmacy data. Again, discovery refutes Plaintiffs' approach. As discussed in more detail below, [redacted] The claims records therefore do

[6] [redacted]

not, and cannot, answer the relevant inquiry under Plaintiffs' class definitions—i.e., what the *net payment* by the Sponsors was (if anything) after deducting the payments by all other entities. Notably, although Plaintiffs assert that the pharmacy data "usually" contains a field identifying the payor, Mem. at 33, the exhibits to which Plaintiffs cite undermine their argument. [redacted]

Furthermore, much of the pharmacy data on which Plaintiffs ask the Court to rely is not available. [redacted] Plaintiffs' failure to obtain such records "heightens the . . . concern that such pharmaceutical records may not be obtainable for use in the ascertainability inquiry." *Wellbutrin*, 308 F.R.D. at 150 (discussing plaintiffs' failure to obtain records despite service of subpoenas during discovery); *accord Carrera*, 727 F.3d at 308–09 (class unascertainable in part because plaintiffs had not obtained during class discovery the retail records that they proposed to use to show diet supplement purchases).

Even without those concrete deficiencies, the very same kinds of records that Plaintiffs tout were held to be insufficient in analogous cases. In *Vista Healthplan*, the plaintiffs provided the customer history of one named consumer plaintiff, which they had obtained from that consumer's pharmacy, and a "chart of claims data that . . . lists patients by number and identifies . . . the submitted cost of the prescription and the copayment paid by the consumer." 2015 WL 3623005, at *9. These records were insufficient because "Plaintiffs have not presented any *evidence* that these records can be utilized to identify class members." *Id.* at *10; *accord*

Wellbutrin, 308 F.R.D. at 150. So too here.

c. Plaintiffs' proposed "method" for excluding single flat copay consumers and fully-insured health plans is not administratively feasible.

Flat Copay Consumers. Plaintiffs purport to exclude single flat copay consumers from their putative class definitions. This obliges them to propose a method for ascertaining which purchasers paid a flat copay and which did not. Yet, as Plaintiffs acknowledge, identifying whether a patient's Thalomid or Revlimid purchase was subject to a flat copay requires a comparison of each purchase receipt or prescription history with the applicable Summary Plan Description ("SPD"), the plan document that explains the coverage terms for that patient for the relevant year. Mem. at 34–35 (suggesting that flat copay consumers can be identified "by comparing the amount and date of the drug purchases listed on her purchase receipt, or the pharmacy- or insurer-supplied prescription history, with the description of the prescription drug benefit provided by her health benefit plan or insurer" (citations omitted)). This is the definition of an "individualized" inquiry. *See, e.g.*, *Vista Healthplan*, 2015 WL 3623005, at *12 (denying class certification on ascertainability grounds where "[m]any individualized questions must be answered in order to determine whether an individual falls within the class definition, such as: . . . What was the individual's copay . . . ?").

Even this individualized inquiry is complex. [redacted] But the reality is not that simple. [redacted]

[redacted]

Plaintiffs' proposed method also presumes the availability and accuracy of Sponsors' SPDs and plan benefit statements. *See* Mem. at 35. But discovery confirmed that such documents are not administratively feasible to review and often are inaccurate. [redacted]

[redacted]

Finally, even assuming the information in the relevant summary plan documents were complete and accurate, one often cannot determine from those documents whether consumers belonging to the plans would be excluded from the classes as uninjured flat copay consumers.

[redacted][7]

Fully-Insured Health Plans. Plaintiffs also purport to exclude fully-insured health plans from the classes. Plaintiffs concede that identifying such plans would require reviewing *each*

[7] The same was true of other named Plaintiffs. [redacted]

Sponsor's individual plan documents, its contracts with its PBMs, or its financial statements, to determine whether it is a class member or not. Mem. at 35–36; Mem. App. D. A method that requires individualized review of every claimant's documents is obviously infeasible.

d. Plaintiffs propose no method for identifying PBM class members.

The *Wellbutrin* plaintiffs "argue[d] that PBMs are not potential class members," and thus did "not need to show that [they] can ascertain which PBMs are class members and which are not." 308 F.R.D. at 148. The court disagreed: "PBMs are potential class members because they may have paid a portion of the retail purchase price . . . via so-called 'spread pricing arrangements' or 'price discount guarantees.'" *Id.* The same reasoning defeats this Motion.

[redacted] That means each Thalomid and Revlimid claim purportedly "paid" by such a Sponsor was paid to the pharmacy in the first instance by the PBM, which later would have sought reimbursement from the Sponsor for some or all of the purchase price pursuant to the parties' contract. If the PBM paid more to the pharmacy than it received in reimbursement from the Sponsor, it would be a class member, as it would have paid a portion of the price after accounting for payments by other entities.

Yet, Plaintiffs fail to provide *any* method, let alone an administratively feasible one, for ascertaining which PBMs bore a portion of the payments for Thalomid and Revlimid. Plaintiffs have not even provided any evidence that would allow one to determine how much each PBM paid to each pharmacy on each transaction. Without this information, Plaintiffs cannot show whether the amount the PBM received in reimbursement from the Sponsor was higher, lower, or the same as the amount the PBM paid—in other words, they cannot show which PBMs (if any) bore a portion of the net purchase price. This is a fatal flaw in Plaintiffs' analysis. "There are

thousands of PBMs and retail pharmacies," and Plaintiffs have not produced any evidence regarding those interactions, let alone "any evidence showing that [they] could synthesize records from these disparate entities and use them to ascertain PBMs . . . in a reliable and administratively feasible manner." *Wellbutrin*, 308 F.R.D. at 150.

Even if Plaintiffs had a method to determine the amounts the PBMs paid to the pharmacies, they cannot account for the other half of the equation: the amounts the Sponsors reimbursed to the PBMs. Discovery has shown the difficulty of such a task, which depends on the terms of the particular contract between the PBM and the Sponsor. [redacted] The contracts governing the relationships between PBMs and Sponsors typically include at least two features that impact the amounts each entity paid toward each prescription: discounts and rebates. Contractual *discount* provisions commonly provide that the PBM will seek reimbursement from the Sponsor for certain medicines at a lower rate than the list price. Contractual *rebate* provisions commonly provide that the PBM will refund to the Sponsor a

[redacted]

portion of the Sponsor's reimbursement price for certain medicines. Ex. 1 (Hughes Rep. ¶ 37).

Plaintiffs have identified no method at all for calculating the net amounts paid by the PBM or the Sponsor for Thalomid and Revlimid prescriptions *after* discounts and rebates are factored in, as would be necessary to determine whether the PBM or Sponsor is a class member. Plaintiffs presumably ignore these questions because answering them requires analyzing every contract between every PBM and every Sponsor—a level of individual inquiry that is incompatible with class certification. And the record shows that this level of inquiry is not possible *even for the named Plaintiffs*:

- [redacted]
- [redacted][11]

[redacted]

[redacted]

[11] [redacted] After the deposition, IUB's counsel represented that each contract continues until the next contract is signed. Ex. 16 (1/26/18 Email from Pruski to Rehns). [redacted]

Ascertaining which PBMs are class members is a complicated but critical aspect of

Plaintiffs' effort to certify the Damages Classes. Plaintiffs' attempt to ignore PBMs, or to assume they do not fall within their class definitions—as some plaintiffs have done in other cases where certification has been denied—should not suffice.

e. Plaintiffs propose no method for ascertaining stop-loss insurance class members.

[redacted] If an insurer paid for some of the Sponsor's members' Thalomid and Revlimid prescriptions, the insurer would be a class member. If, on the other hand, the insurer did not pay for any prescriptions (for example, because the Sponsor did not incur enough in medical costs in the relevant year for the insurance policy to kick in), it would not be a class member. By the same token, if the stop-loss insurance covered *all* of the Sponsor's costs for the brand, and would have done so for a generic equivalent as well, then the insurer is a class member but *the Sponsor is not a class member*. Yet, Plaintiffs offer no method whatsoever of ascertaining these facts.

Plaintiff Local 39 is a good example. [redacted] (Local 39 does not allege that any of its members took Thalomid. Am. Compl. ¶ 14.) [redacted]

f. Plaintiffs propose no method for ascertaining which purchases fall within the relevant jurisdictions' laws.

The proposed Damages Classes are limited to persons or entities that purchased or paid for Thalomid or Revlimid in the fourteen Damages Jurisdictions. Mem. at 1. It is therefore fundamental to their Motion that Plaintiffs articulate a method to identify the purchases of Thalomid and Revlimid covered by the Damages Jurisdictions while excluding other purchases.

[redacted]

Plaintiffs offer no method for determining which purchases fall within the jurisdictions at issue. Indeed, Plaintiffs do not even appear to apply consistent criteria to decide which state's laws apply to a given purchase—let alone a workable method to determine whether those criteria are satisfied. [redacted]

Plaintiffs try to bring Mr. Mitchell's claims under District of Columbia law, alleging that he "received monthly counseling from a nurse who read a list of cautions to him over the telephone from his office in Washington, D.C." and "received shipments of Revlimid to his office in Washington, D.C." Am. Compl. ¶ 16. Mr. Mitchell does not have standing to bring claims under District of Columbia law. *See infra* pp. 45–49. But even if he did, Plaintiffs could not

demonstrate a feasible method for identifying which other class members received phone calls from providers in Damages Jurisdictions or received shipments to Damages Jurisdictions.

By contrast, some of the named Plaintiffs are bringing claims only where their members resided. NEC, for example, alleges claims on behalf of "its members in Massachusetts and Maine," NEC Compl. ¶ 12,[13] [redacted]. Providence, for example, alleges claims on behalf of "its members in Florida, Kansas, Massachusetts, New Jersey, North Carolina, Rhode Island, and Pennsylvania," Am. Compl. ¶ 13, [redacted]. Similarly, DEA alleges claims on behalf of "its members in Florida, Michigan, New Jersey, New York, North Carolina, Oregon, Pennsylvania and Tennessee," Am. Compl. ¶ 15, [redacted]

These inconsistencies underscore the difficulty of making class-wide determinations

[13] "NEC Compl." refers to Plaintiffs' Complaint filed on September 28, 2017 in the matter captioned *New England Carpenters Health Benefits Fund v. Celgene Corp.*, No. 17-cv-07637 (D.N.J.), which was consolidated with this action on December 26, 2017, *see* (Dkt. 174).

about whether a class member paid for a portion of the purchase price for Thalomid or Revlimid in a Damages Jurisdiction. But that is not the end of the inquiry: To determine whether any particular state allows claims to be brought by, for example, consumers who have no connection to the state other than ordering a prescription by mail from a pharmacy in that state, one must conduct an analysis of the state's laws. *See, e.g.*, *In re Flonase Antitrust Litig.*, 692 F. Supp. 2d 524, 533, 537–38 (E.D. Pa. 2010) (analyzing whether out of state purchasers may bring claims under Florida law); *In re Wellbutrin XL Antitrust Litig.*, 260 F.R.D. 143, 158–67 (E.D. Pa. 2009) (evaluating indirect purchaser claims under the laws of the various states under which claims were brought). Plaintiffs have not offered such an analysis for any of the Damages Jurisdictions.

B. PLAINTIFFS CANNOT DEMONSTRATE PREDOMINANCE.

Rule 23(b)(3)'s "predominance" component examines "whether common issues of law or fact in the case predominate over non-common, individualized issues of law or fact." *Neale v. Volvo Cars of N. Am., LLC*, 794 F.3d 353, 370 (3d Cir. 2015). The "predominance requirement 'tests whether proposed classes are sufficiently cohesive to warrant adjudication by representation,'" *Marcus*, 687 F.3d at 600 (quoting *Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 623 (1997)), and is "far more demanding" than the commonality requirement of Rule 23(a), *Amchem*, 521 U.S. at 623–24. "To assess predominance, a court at the certification stage must examine each element of a legal claim through the prism of Rule 23(b)(3)." *Marcus*, 687 F.3d at 600 (internal quotation marks omitted). "If proof of the essential elements of the cause of action requires individual treatment, then class certification is unsuitable." *In re Hydrogen Peroxide Antitrust Litig.*, 552 F.3d 305, 311 (3d Cir. 2008) (internal quotation marks omitted).

Plaintiffs have not satisfied their burden to show predominance for three reasons. *First*, Plaintiffs cannot prove injury on a class-wide basis because the proposed classes include large

numbers of uninjured persons and entities, whom Plaintiffs cannot distinguish from injured class members without resort to individualized inquiry. *Second*, Plaintiffs' proposed class-wide damages analysis inflates damages and cannot be corrected without individualized analysis. *Third*, significant variations in the state laws governing Plaintiffs' unjust enrichment and consumer protection claims would render any class-wide trial impractical.

1. Numerous Proposed Class Members Have Not Suffered Injury.

Injury is an essential element of an antitrust claim. *See, e.g., In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 164 (3d Cir. 2017) ("[t]o establish antitrust standing, a plaintiff must show that it has suffered an antitrust injury"). To certify a class, therefore, "the putative class must first demonstrate economic loss—that is, the fact of damage—on a common basis." *Harnish v. Widener Univ. Sch. of Law*, 833 F.3d 298, 305–06 (3d Cir. 2016) (internal quotation marks omitted); *see also In re Rail Freight Fuel Surcharge Antitrust Litig.*, 725 F.3d 244, 252 (D.C. Cir. 2013) ("plaintiffs must also show that they can prove, through common evidence, that all class members were in fact injured"). The same is true for Plaintiffs' state law unfair competition and unjust enrichment claims. *See Gonzalez v. Corning*, 317 F.R.D. 443, 517 (W.D. Pa. 2016) (denying certification of, *inter alia*, unjust enrichment claims where "plaintiffs failed to meet their burden to establish that injury can be proven by evidence that is common to the proposed [] class"); *Ackerman v. Coca-Cola Co.*, No. 09 CV 395 DLI RML, 2013 WL 7044866, at *20 & n.31 (E.D.N.Y. July 18, 2013) (denying certification of damages class for unjust enrichment and unfair trade practices for failure to propose "a suitable methodology or formula for establishing causation and injury on a class-wide basis").

Particularly in antitrust cases, "impact often is critically important for the purpose of

evaluating Rule 23(b)(3)'s predominance requirement because it is an element of the claim that may call for individual, as opposed to common, proof." *Hydrogen Peroxide*, 552 F.3d at 311; *see also Am. Seed Co. v. Monsanto Co.*, 271 F. App'x 138, 140 (3d Cir. 2008) (proof of antitrust impact can be made on common basis "'so long as the common proof adequately demonstrates some damage to each individual'" (quoting *Bogosian v. Gulf Oil Corp.*, 561 F.2d 434, 454 (3d Cir. 1977)). Failure to demonstrate fact of injury on a class-wide basis is fatal to class certification. *See, e.g.*, *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 190 (3d Cir. 2001) (affirming decision not to certify where "ascertaining which class members have sustained injury means individual issues predominate over common ones").

Because there are large categories of uninjured class members that Plaintiffs have not identified—and cannot identify without extensive individualized inquiry—Plaintiffs' Motion should be denied on predominance grounds.

a. Uninjured Consumers and TPPs.

The proposed classes include vast numbers of consumers and third party payors ("TPPs") who paid for part or all of the purchase price for Thalomid or Revlimid but are uninjured by Celgene's alleged conduct because they would not have paid less if generic versions of these medicines had been available. These include:

Consumers Who Would Continue to Purchase Brand Thalomid or Revlimid.

[redacted] Class members who would continue

to take brand products are indisputably uninjured, but Plaintiffs offer no method for identifying which consumers would continue to take brand Thalomid or Revlimid and which would not. [redacted] The court in *Vista Healthplan* specifically noted the presence of brand loyalists as a significant barrier to class certification in a case like this: "[W]hen every class member has the potential to be a brand loyalist, a person with a flat copay or a consumer who never paid out-of-pocket for their prescriptions, and the only way to identify persons who fall within those groups is individualized inquiry, individualized inquiries would predominate." 2015 WL 3623005, at *19.

Consumers Who Hit Their OOP Maximums. Consumers who would have hit their OOP maximums even with a generic alternative are not injured. Plaintiffs do not attempt to estimate the number of such consumers, but it is likely to be high. [redacted]

Consumers Who Pay the Same for a Generic and a Brand. Consumers who would have paid the same amount for the generic as they paid for the brand are uninjured. This can happen in various ways even if the consumer does not have a flat copay. As discussed above, a health plan may include certain generic medications on the brand tier, meaning that consumers would have the same copayment for the generic versions of those drugs as for the brand versions. *Supra* p. 21. Similarly, consumers often have a cap on the amount of coinsurance they owe for specialty drugs like Thalomid and Revlimid. If a plan included a generic Thalomid or Revlimid on the specialty drug tier, consumers would likely hit that cap when purchasing the generic drug as well, resulting in the same payment for either the brand or the generic. *Id*.

Consumers Who Obtain Patient Assistance. Celgene offers patient assistance programs that reduce the amounts that insured and uninsured patients are charged for Thalomid and Revlimid. Such patient assistance can cause consumers to pay less for the brand medication than they would have paid for the generic alternative, and these consumers are not injured. [redacted] Plaintiffs offer no method for identifying members of this significant group of uninjured consumers. *See* Ex. 1 (Hughes Rep. ¶ 15 n.13) (between 2007 and 2016, Celgene provided at least $567.9 million in patient assistance for Thalomid and Revlimid).

Plan Sponsors with Stop-Loss Insurance. Sponsors who would have hit their stop-loss deductibles even with a generic alternative are not injured because they would have paid the same deductible amounts. [redacted]

[redacted]

Plan Sponsors and PBMs Who Pay the Same or Less for a Brand than a Generic. Sponsors that would pay the same or less for a brand than a generic because of the discount or rebate structures in their contracts with their PBMs would not be injured. [redacted] If those discounts and rebates result in a net price that is lower than the generic price the PBM would have paid, the PBM would not be injured. Plaintiffs offer no method for identifying such Sponsors and PBMs, which would require an individualized analysis into each Sponsor's contract with its PBM for each year, as well the contracts between PBMs and pharmacies and drug manufacturers.

Plan Sponsors with Maximum Plan Limits. Sponsors whose members taking Thalomid and Revlimid would have hit their plan limit maximums even with a generic alternative are not

injured. The number of such Sponsors is likely to be high in Plaintiffs' proposed classes for the same reasons that many consumers would hit their OOP maximums: cancer medications, including generic cancer medications, are expensive and are often used in conjunction with other costly medical benefits. [redacted] If a DEA member would have incurred costs in excess of that amount regardless of whether she was taking a generic version of Revlimid, DEA would not be injured with respect to that member's claims. Yet, Plaintiffs have not identified a method for identifying such Sponsors.

b. Large Numbers of Uninjured Class Members Preclude Certification.

The presence of these numerous uninjured consumers and TPPs, whose identities cannot be determined without individual inquiry, precludes a finding of predominance under Rule 23(b)(3). Many courts have so found. *See, e.g.*, *Newton*, 259 F.3d at 178 (affirming denial of class certification where district court "concluded that an undefined number of class members sustained no economic loss whatsoever, necessitating the conclusion that damages were not susceptible to class-wide proof"); *Harnish*, 833 F.3d at 313 (affirming decision not to certify proposed class where "the inability to resolve [the fact of damages] in class-wide fashion will cause individual questions to predominate over common ones"); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline*, No. 04-5898, 2010 WL 3855552, at *28 (E.D. Pa. Sept. 30, 2010) (declining to certify class where there were "a great number of uninjured class members" and plaintiffs "failed to show they c[ould] exclude th[o]se uninjured consumers").[14]

[14] *See also Processed Egg Prods.*, 312 F.R.D. at 157 (existence of contracts "potentially immune from the conspiracy, the prevalence and mechanics of which have not been adequately addressed by Plaintiffs, weigh[ed] against class certification"); *In re Intel Corp. Microprocessor Antitrust Litig.*, No. 05-1717-LPS, 2014 WL 6601941, at *13 (D. Del. Aug. 6, 2014) (declining to certify

[redacted]—a significant number that would itself defeat predominance. *See, e.g.*, *Vista Healthplan*, 2015 WL 3623005, at *19 (where "five percent of consumers had no out-of-pocket payment" and there was a "substantial likelihood" of other uninjured class members, "prevalence of uninjured class members [wa]s more than de minimis"); *In re Rail Freight Fuel Surcharge Antitrust Litig.*, No. 1869, -- F. Supp. 3d --, 2017 WL 5311533, at *88 (D.D.C. Nov. 13, 2017) (finding 12.7 percent uninjured class members "beyond the outer limits of what can be considered *de minimis* for purposes of establishing predominance"). But that [redacted] estimate is not even close to the full extent of uninjured class members considering the many categories described above. Plaintiffs' proposed Damages Classes therefore "should not be certified [because] it is apparent that [they] contain[] a great many persons who have suffered no injury at the hands of the defendant." *Sheet Metal Workers*, 2010 WL 3855552, at *28 (internal quotation marks omitted).

2. Plaintiffs' Proposal to Calculate Damages on a Class-Wide Basis Is Fundamentally Unreliable.

As Plaintiffs observe, at the class certification stage, they "'must show that a reliable method is available to prove damages on a class-wide basis.'" Mem. at 44 (quoting *In re Processed Egg Prods. Antitrust Litig.*, 312 F.R.D. 124, 202 (E.D. Pa. 2015)); *see also Comcast Corp. v. Behrend*, 569 U.S. 27, 35 (2013) ("a model purporting to serve as evidence of damages in [a] class action must measure only those damages attributable to" theory "accepted for class-action treatment"). Dr. Leitzinger's damages methodology fails this requirement. Rather than

where plaintiffs failed to offer "common proof" that "all or nearly all class members suffered antitrust injury").

accounting for the many complexities in the pharmaceutical payment marketplace, [redacted] *See Comcast*, 569 U.S. at 34 (predominance requirement not met where "[q]uestions of individual damage calculations will inevitably overwhelm questions common to the class"); *In re Rail Freight*, 2017 WL 5311533, at *59–61 (evidence that large portion of class traffic in plaintiffs' damages model was not subject to the alleged fuel overcharges undermined model's reliability).

a. Dr. Leitzinger's Failure Adequately to Identify Transactions by Class Members Inflates Damages.

The Supreme Court in *Comcast* recognized that a class-wide damages model is invalid if it "identifies damages that are not the result of the wrong." *Comcast*, 569 U.S. at 37; *see also Franco v. Conn. Gen. Life Ins.*, 299 F.R.D. 417, 430 (D.N.J. 2014) (court must ensure that "proffered model measures only those damages attributable to the plaintiff's theory of liability"), *aff'd*, 647 F. App'x 76 (3d Cir. 2016). Courts must review an expert's methodology to determine if it is "a just and reasonable inference or speculative." *Comcast*, 569 U.S. at 35.

[redacted]

Dr. Leitzinger's model does not accurately reflect the transactions that are attributable to Plaintiffs' theory of class injury, in at least three significant respects:

First, Dr. Leitzinger's model does not reliably identify those purchases of Thalomid or Revlimid that occurred in the fourteen Damages Jurisdictions. [redacted]

[redacted] To the extent Plaintiffs take the position that PBMs are not part of the Damages Classes, Dr. Leitzinger fails to identify and subtract costs borne by PBMs, which inflates his damages estimate for those payors who *are* class members.

Third, Dr. Leitzinger's model does not reliably estimate the amount of Medicare reimbursement. Plaintiffs' proposed classes exclude government payors such as Medicare. Mem. at 1 n.1. [redacted] presumably because identifying those facts requires individualized inquiry into the status of the covered consumers and the level of their coverage. Dr. Leitzinger's failure to identify and exclude these non-class member payments weighs heavily against the reliability of his model to measure damages to purported class members.

b. The Individualized Damages Issues Predominate.

Plaintiffs' failure to analyze or incorporate individualized differences in their damages model defeats predominance. Courts routinely deny class certification in similar circumstances. In *Processed Egg Products*, the court denied certification where it found that pricing was "far more individualized and complex than [the plaintiff's expert's] single-pass-through model acknowledges and can accommodate." 312 F.R.D. at 160–61. In *Sheet Metal Workers*, the court found certification unwarranted where—as in this case—the proposed model used average prices, thereby "glid[ing] over what may be important differences" in the "actual price paid by

each purported class member." 2010 WL 3855552, at *30 (internal quotation marks omitted).[16]

Equally problematic is Dr. Leitzinger's inflation of damages estimates. As discussed above, such inflation is not merely an issue of allocation among class members, but rather a misalignment of Plaintiffs' theory of liability and their proposed damages. Under *Comcast* and its progeny, this precludes certification. *E.g.*, *Comcast*, 569 U.S. at 37; *Wellbutrin XL*, 308 F.R.D. at 149 (expressing doubt that model that "would potentially include damages suffered by non-class members, and may therefore overstate the amount of damages suffered," could satisfy requirement that damages be "'susceptible to measurement across the entire class'").

3. Substantial Variation Among Applicable State Laws Defeats Predominance.

Plaintiffs' proposed classes include claimants under the laws of all fourteen Damages Jurisdictions, based on state antitrust and consumer protection statutes and common law unjust enrichment. *See* Mem. at 1; Mem. App. E. "In a motion for class certification, plaintiff bears the burden of providing an extensive analysis of state law variations to determine whether there are insuperable obstacles to class certification." *Lyon v. Caterpillar, Inc.*, 194 F.R.D. 206, 219 (E.D. Pa. 2000) (internal quotation marks omitted). Plaintiffs assert that "any differences between the[ir] state law claims are insignificant" because the state laws have "virtually identical elements." Mem. at 46–47. Plaintiffs' analysis ignores the many differences among state laws that have led other courts to deny certification of similar proposed classes. *See*, *e.g.*, *Processed*

[16] *See also Grandalski v. Quest Diagnostics Inc.*, 767 F.3d 175, 185 (3d Cir. 2014) (affirming refusal to certify unjust enrichment class because "individual inquiries" would be required "to determine whether an alleged overbilling constituted unjust enrichment for each class member"); *In re Pharmacy Benefit Managers Antitrust Litig.*, Nos. 06-1782 et al., 2017 WL 275398, at *31 (E.D. Pa. Jan. 18, 2017) (denying certification where economic model "failed to isolate the difference in reimbursement rates attributable to an alleged antitrust conspiracy from any difference attributable to legitimate bargaining power or other market factors").

Egg Prods., 312 F.R.D. at 163 & n.31 (rejecting certification of unjust enrichment class with "essentially identical" elements because plaintiffs failed to analyze whether elements were "capable of common proof").

a. Unjust Enrichment.

As set forth in Appendix A, there are significant variations in state unjust enrichment laws that preclude a finding of predominance. For example, states differ with respect to: (1) whether and how they recognize unjust enrichment as an independent cause of action, as opposed to requiring a separate underlying cause of action; (2) what conduct is required to prove a claim, including whether a plaintiff must prove inducement, solicitation, fraud, or inadequate consideration or compensation; (3) whether a relationship between the parties or a direct conferral of benefit is required; (4) whether a plaintiff must prove a defendant's culpable state of mind; (5) the length of the statute of limitations period, and when the limitations period begins to run; and (6) whether an adequate remedy at law precludes an unjust enrichment claim. *See* App. A (describing variations across all fourteen Damages Jurisdictions).

Examples from Plaintiffs' Appendix E reveal some examples of the wide-ranging differences among the applicable state laws:

- Regarding New York law, Plaintiffs cite a case stating that a plaintiff "need not be in privity with the defendant to state a claim for unjust enrichment." Mem. App. E at 20 (citing *Sperry v. Crompton Corp.*, 863 N.E.2d 1012, 1018 (N.Y. 2007). But that very case affirmed that New York law *does* require a relationship between parties that is not "too attenuated." *Sperry*, 863 N.E.2d at 1018. New York's relationship requirement for unjust enrichment distinguishes it from other states without a similar requirement.[17] That distinction is significant here, because the putative class members are *indirect* purchasers and had no direct

[17] For example, in *Sheet Metal Workers Local 441 Health and Welfare Plan v. GlaxoSmithKline, PLC*, 263 F.R.D. 205 (E.D. Pa. 2009), the court granted the defendants' motion for judgment on the pleadings for unjust enrichment claims under New York law, finding that indirect purchasers of a drug had "no relationship" with the product manufacturer, but it denied similar motions for claims under Illinois and Alabama law based on this distinction. *Id.* at 216–18.

relationship with Celgene.

- Plaintiffs contend that "Florida law does not appear to require the conferral of a direct benefit exclusively." Mem. App. E at 16 (citing *In re Processed Egg Prods. Antitrust Litig.*, 851 F. Supp. 2d 867, 929 (E.D. Pa. 2012)). But Florida courts have held that a direct conferral of benefit *is* required. *See, e.g.*, *Wiand v. Waxenberg*, 611 F. Supp. 2d 1299, 1310 (M.D. Fla. 2009) ("Florida law provides that a plaintiff must directly confer a benefit on the defendant in order to recover pursuant to an unjust enrichment theory."); *Peoples Nat'l Bank of Commerce v. First Union Nat'l Bank of Fla., N.A.*, 667 So. 2d 876, 879 (Fla. Dist. Ct. App. 1996) (per curiam) (affirming dismissal of unjust enrichment claim where plaintiff "could not and did not allege that it had directly conferred a benefit on the defendants").

In light of these widespread variations, many courts have rejected attempts to certify classes under the same unjust enrichment laws Plaintiffs invoke. For example, in *In re Actiq Sales and Marketing Practices Litigation*, the court cited important differences in states' common law concerning "the availability of unjust enrichment as an independent cause of action, the need to show an absence of an adequate remedy at law, the requirement that a benefit be obtained at the direct expense of the plaintiff, the level of misconduct a plaintiff must prove, and the availability of defenses such as unclean hands and laches." 307 F.R.D. 150, 163, 165–66 (E.D. Pa. 2015) (footnotes omitted). The court found that the plaintiffs' efforts to overcome these differences by grouping the various laws "still d[id] not account for individual fact issues such that common issues predominate." *Id.* at 169. Other courts agree. *See, e.g.*, *Vista Healthplan*, 2015 WL 3623005, at *30, *33 (concluding that plaintiffs' unjust enrichment claims were "not amenable" to grouping); *Sheet Metal Workers Local 441 Health & Welfare Plan v. GlaxoSmithKline, PLC*, 737 F. Supp. 2d 380, 430–32, 441, 445–46 (E.D. Pa. 2010) (dismissing state law unjust enrichment claims for lack of indirect purchaser standing and/or failure to state a claim where unjust enrichment was not a separate cause of action); *Processed Egg Prods.*, 312 F.R.D. at 163 & n.31 (declining certification where plaintiffs "provided citations to the elements of unjust enrichment in [the 17] states, but . . . have not sufficiently analyzed whether

these elements are capable of common proof").

Plaintiffs cite *Sullivan v. DB Investments, Inc.* for the proposition that "'variations in the rights and remedies available to injured class members under the various laws of the fifty states [do] not defeat commonality and predominance.'" Mem. at 47 (quoting 667 F.3d 273, 301 (3d Cir. 2011)). That case, however, concerned *settlement* classes—not litigation classes. *Sullivan*, 667 F.3d at 285.[18] As the *Sullivan* court observed, "'the class settlement posture of th[at] case largely marginalize[d] the objectors' concern that state law variations undermine a finding of predominance.'" *Id.* at 302–03; *id.* at 303 ("Because we are presented with a settlement class certification, we are not as concerned with formulating some prediction as to how [variances in state law] would play out at trial, for the proposal is that there be no trial." (internal quotation marks omitted)); *see also Neale*, 794 F.3d at 372 ("In *Sullivan II*, looking at the class claims was particularly unwarranted in the settlement context since a district court need not envision the form that a trial would take, nor consider the available evidence and the method or methods by which plaintiffs propose to use the evidence to prove the disputed element at trial." (internal quotation marks omitted)).

b. Unfair and Deceptive Trade Practices.

As with unjust enrichment, there are extensive variations among state laws concerning

[18] Plaintiffs also cite *In re Prudential Insurance Co. America Sales Practice Litigation Agent Actions*, 148 F.3d 283, 315 (3d Cir. 1998), *In re School Asbestos Litigation*, 789 F.2d 996, 1010 (3d Cir. 1986), and *In re Lidoderm Antitrust Litigation*, No. 14-md-2521, 2017 WL 679367, at *27 (N.D. Cal. Feb. 21, 2017). Like *Sullivan*, *Prudential* concerned a settlement class. 148 F.3d at 307. In *School Asbestos*, the Third Circuit declined to revisit the district court's decision that differences in applicable state laws did not present "insuperable obstacles," though it noted that it "ha[d] some doubt on this score." 789 F.2d at 1010. And *Lidoderm* addressed state antitrust laws that are "interpreted consistently with federal antitrust law (and therefore will rise and fall with the [plaintiffs'] Sherman Act claims)," 2017 WL 679367, at *27, not the consumer protection and unjust enrichment claims at issue here.

consumer protection and unfair trade practices that make them unsuitable for class treatment. For example, jurisdictions vary regarding: (1) whether the law requires a showing of false or deceptive acts; (2) whether the conduct must be directed at consumers; (3) whether the defendant must act willfully or with intent to deceive; (4) whether the conduct must occur locally; (5) whether corporations, business entities, or third parties not directly involved in the alleged deceptive transaction can bring claims; (6) whether and to what extent a plaintiff must prove reliance on the alleged deceptive conduct; (7) the types of damages available; and (8) the length of the statute of limitations period and when it begins to run. *See* App. B (describing variations across all fourteen jurisdictions at issue).

As one example, Plaintiffs' Appendix E cites two New York cases for the proposition that "indirect purchaser actions" are permitted. Mem. App. E at 12 (citing *Vitolo v. Dow Corning Corp.*, 166 Misc. 2d 717 (N.Y. Sup. Ct., Richmond Co. 1995) and *In re Methyl Tertiary Butyl Ether Prods. Liab. Litig.*, 175 F. Supp. 2d 593 (S.D.N.Y. 2001)). Plaintiffs' chart fails to note that "[t]o make out a prima facie case under [New York] Section 349, a plaintiff must demonstrate that (1) the defendant's deceptive acts *were directed at consumers*, (2) the acts are misleading in a material way, and (3) the plaintiff has been injured as a result." *Maurizio v. Goldsmith*, 230 F.3d 518, 521 (2d Cir. 2000) (per curiam) (emphasis added) (dismissing claim under Section 349 because alleged conduct was not "consumer-oriented" or "intended to deceive consumers in a material way"); *see also Sheet Metal Workers*, 737 F. Supp. 2d at 418 (dismissing end-payor claims that pharmaceutical manufacturer prevented entry of generic product under New York's Section 349 as insufficiently consumer-oriented). Other states' laws contain different requirements (for example, focusing on a defendant's intent). *See, e.g.*, *Sheet Metal Workers*, 737 F. Supp. 2d at 413 (dismissing claim under Michigan Consumer Protection

Act for failure to allege that defendant "had the intent to deceive consumers").

Courts have denied certification when plaintiffs sought to lump these different laws together into a single class. In *In re Ford Motor Co. Ignition Switch Products Liability Litigation*, 194 F.R.D. 484 (D.N.J. 2000), the court noted differences such as privity requirements, what constitutes actionable conduct, and the definition of protected "consumers" in concluding that "common legal issues do not predominate." *Id.* at 489–90. In *Grandalski*, the court affirmed a district court's decision not to certify a class of claims under state "unfair and deceptive" conduct and "consumer fraud" statutes, noting that plaintiffs "must do more than provide their own *ipse dixit*, citation to a similar case, and a generic assessment of state consumer fraud statutes, to justify grouping." 767 F.3d at 184. Other courts have reached similar conclusions. *See Lyon*, 194 F.R.D. at 219 ("[s]tate consumer protection acts vary on a range of fundamental issues," including prohibited conduct, scienter, and availability of class actions); *S. States Police Benevolent Ass'n v. First Choice Armor & Equip., Inc.*, 241 F.R.D. 85, 93 (D. Mass 2007) (denying certification of subclass of individuals under the consumer protection statutes of eight states, including California, Florida, Massachusetts, and New York, because "variances in the substantive prerequisites of such claims" made the subclass "unmanageable and contrary to the fair and efficient adjudication of th[e] matter"); *Mazza v. Am. Honda Motor Co.*, 666 F.3d 581, 591 (9th Cir. 2012) (denying certification after examining the differing elements—such as scienter and reliance—of certain state consumer protection statutes, including California, Florida, New York, and Pennsylvania).

C. NAMED PLAINTIFF DAVID MITCHELL DOES NOT SATISFY THE ADEQUACY OR TYPICALITY REQUIREMENTS OF RULE 23(A).

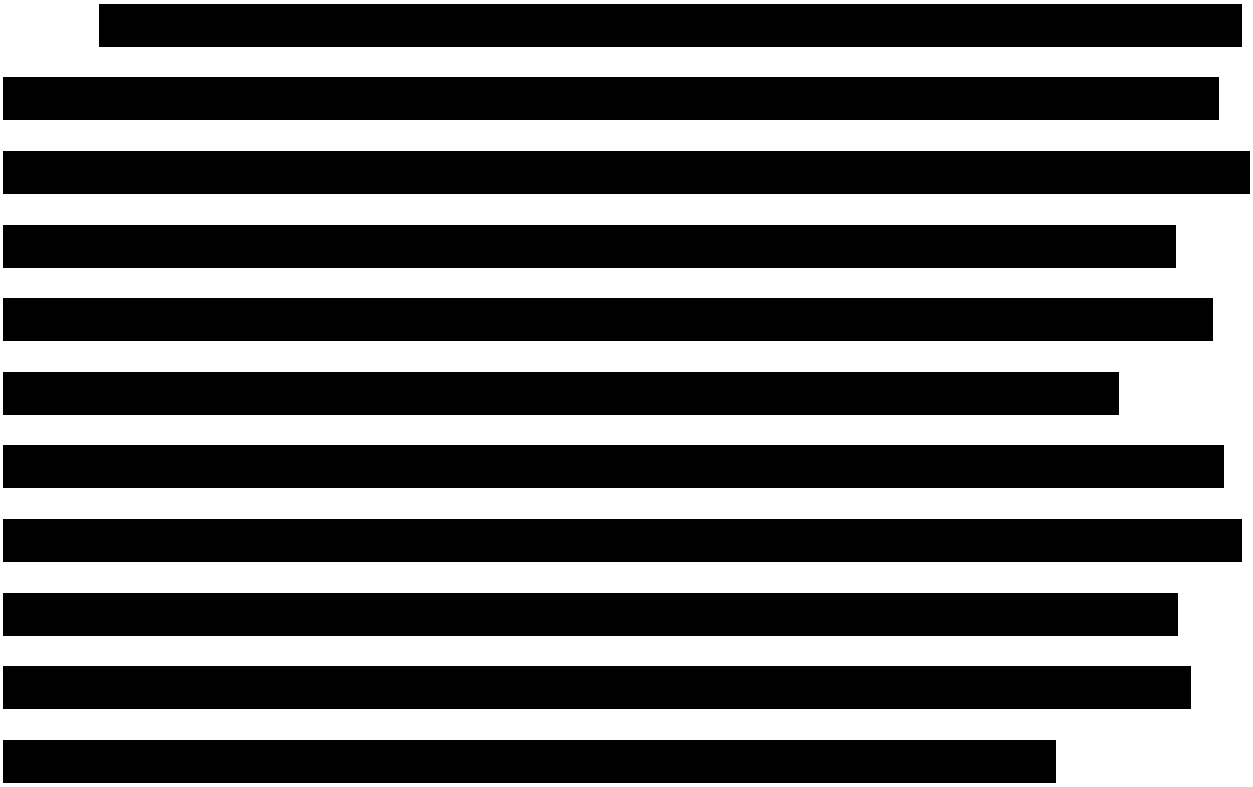
Plaintiffs proffer six class representatives in this action, but only one is a consumer: David Mitchell. Mr. Mitchell is not an adequate class representative because he does not have

standing to pursue any of the claims asserted in this case. Accordingly, even if the Court were inclined to certify a class, Mr. Mitchell should not be certified as a class representative and his claims should be dismissed.

"It is well settled that to be a class representative on a particular claim, the plaintiff must himself have a cause of action on that claim." *Zimmerman v. HBO Affiliate Grp.*, 834 F.2d 1163, 1169 (3d Cir. 1987). If a class representative does not have individual standing, his claims cannot be typical of those of the proposed class nor can he adequately represent the class. *See McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 223 (3d Cir. 2012) ("'It should be obvious that there cannot be adequate typicality between a class and a named representative unless the named representative has individual standing to raise the legal claims of the class.'" (quoting *Prado-Steiman ex rel. Prado v. Bush*, 221 F.3d 1266, 1279 (11th Cir. 2000))); *see also Rector v. City & Cty of Denver*, 348 F.3d 935, 949–50 (10th Cir. 2003) (same).

1. Mr. Mitchell Does Not Have Standing to Pursue Damages Claims Under District of Columbia Law.

Courts repeatedly have held that "named plaintiffs lack standing to assert claims under the laws of the states in which they do not reside or in which they suffered no injury." *In re Niaspan Antitrust Litig.*, 42 F. Supp. 3d 735, 758 (E.D. Pa. 2014) (internal quotation marks omitted); *see also In re Flonase Antitrust Litig.*, 284 F.R.D. 207, 215 (E.D. Pa. 2012) ("Indirect Purchasers cannot attempt to expand their class to include states in which no named plaintiff has demonstrated injury . . . ."); *In re Packaged Ice Antitrust Litig.*, 779 F. Supp. 2d 642, 657 (E.D. Mich. 2011); *In re Ductile Iron Pipe Fittings ("DIPF") Indirect Purchaser Antitrust Litig.*, No. 12-169, 2013 WL 5503308, at *11 (D.N.J. Oct. 2, 2013); *McGuire v. BMW of N. Am., LLC*, No. 13-7356, 2014 WL 2566132, at *6–7 (D.N.J. June 6, 2014). Under these principles, Mr. Mitchell cannot assert a claim under D.C. law.



Plaintiffs allege that Mr. Mitchell "received monthly counseling from a nurse who read a list of cautions to him over the telephone from his office in Washington, D.C." and "received shipments of Revlimid to his office in Washington, D.C." Am. Compl. ¶ 16. These allegations are insufficient to establish standing in the District of Columbia because his claim is based on his *payments* for Revlimid, not the counseling or shipping. *See In re Capacitors Antitrust Litig.*, 154 F. Supp. 3d 918, 927–28 (N.D. Cal. 2015) (rejecting argument that plaintiff should having standing to pursue claims under the laws of states where deliveries were received because "[j]ust receiving deliveries of price-fixed goods that were purchased elsewhere does not constitute an Article III injury-in-fact under the antitrust or consumer protection laws").

Without a claim under District of Columbia law (or any of the other Damages Jurisdictions), Mr. Mitchell cannot represent a class of plaintiffs with such claims. And because no other named Plaintiff claims to have suffered injury in the District of Columbia, no class of

D.C. purchasers may be certified. *See Zimmerman*, 834 F.2d at 1169; *In re Magnesium Oxide Antitrust Litig.*, No. CIV. 10-5943 DRD, 2011 WL 5008090, at *10 (D.N.J. Oct. 20, 2011) (dismissing claims under state laws for which named plaintiffs lack standing); *In re Suboxone (Buprenorphine Hydrochloride & Naloxone) Antitrust Litig.*, 64 F. Supp. 3d 665, 692–94 (E.D. Pa. 2014) (same); *In re Flash Memory Antitrust Litig.*, 643 F. Supp. 2d 1133, 1164 (N.D. Cal. 2009) (same); *In re Flonase*, 284 F.R.D. at 215 (indirect purchaser class "can only consist of individuals and entities that purchased and/or reimbursed for [the product] in . . . states in which at least one named plaintiff has demonstrated injury").

2. Mr. Mitchell Does Not Have Standing to Seek an Injunction.

Plaintiffs' proposed Injunction Class comprises persons or entities who paid a portion of the purchase price for Thalomid and Revlimid. *See* Mem. at 1. To have standing to seek injunctive relief, a plaintiff must show: (1) that he is under imminent threat of suffering injury in fact "'that is concrete and particularized'"; (2) "a causal connection between the injury and the conduct complained of"; and (3) "a likelihood that a favorable judicial decision will prevent or redress the injury." *ZF Meritor, LLC v. Eaton Corp.*, 696 F.3d 254, 301 (3d Cir. 2012) (quoting *Summers v. Earth Island Inst.*, 555 U.S. 488, 493 (2009)). "Even if the plaintiff has suffered a previous injury due to the defendant's conduct, the equitable remedy of an injunction is 'unavailable absent a showing of irreparable injury, a requirement that cannot be met where there is no showing of any real or immediate threat that the plaintiff will be wronged again[.]'" *Id.* (alteration in original) (quoting *City of Los Angeles v. Lyons*, 461 U.S. 95, 111 (1983)).

The Third Circuit repeatedly has held that a plaintiff seeking an injunction must show that he was "*likely* to suffer future injury"; a mere "possibility" of future injury is insufficient. *Id.* at 302. In *In re New Jersey Title Insurance Litigation*, 683 F.3d 451 (3d Cir. 2012), title insurance purchasers filed antitrust claims against a number of title insurance companies for

allegedly conspiring to fix title insurance rates. The Third Circuit held that the plaintiffs lacked standing to seek an injunction, in part because they "did not assert that they intend[ed] to re-purchase title insurance" and, although they claimed that owners generally relocate every seven years, "fail[ed] to raise their claims above the speculative level." *Id.* at 461; *see also McNair v. Synapse Grp. Inc.*, 672 F.3d 213, 225–26 (3d Cir. 2012) ("[T]he wholly conjectural future injury Appellants rely on does not, and cannot, satisfy the constitutional requirement that a plaintiff seeking injunctive relief must demonstrate a likelihood of future harm."); *Smith v. Chrysler Fin. Co.*, No. 00–cv–6003, 2004 WL 3201002, at *4 (D.N.J. Dec. 30, 2004) ("The injury which Plaintiffs allege, that they may want to buy another Chrysler in the future and may be discriminated against by Defendant, is simply too speculative . . . .").

[redacted] There is no allegation, much less evidence, that Mr. Mitchell will take Thalomid or Revlimid in the future. Under these circumstances, where Mr. Mitchell is not likely to suffer future injury based on Celgene's alleged anticompetitive conduct, and any such injury would be entirely speculative, Mr. Mitchell lacks standing to pursue injunctive relief and is not an adequate class representative for an injunctive class.

D. PLAINTIFFS' INJUNCTION CLASS CANNOT BE CERTIFIED BECAUSE THE RELIEF SOUGHT IS PRIMARILY MONETARY.

Plaintiffs' efforts to certify a nationwide Injunction Class also fail. It is well settled that certification under Rule 23(b)(2) should be denied where, as here, the relief sought is primarily monetary. *See Beck v. Maximus, Inc.*, 457 F.3d 291, 301 (3d Cir. 2006) (Rule 23(b)(2) "does not extend to cases in which the appropriate final relief relates exclusively or predominantly to money damages" (quoting Fed. R. Civ. P. 23(b)(2) advisory committee's note)). Courts have thus consistently deemed certification under Rule 23(b)(2) improper where "the relief sought . . .

is predominantly money damages," *In re Arthur Treacher's Franchise Litig.*, 93 F.R.D. 590, 594 (E.D. Pa. 1982), or "where antitrust plaintiffs seek treble damages, . . . even if injunctive relief is sought as well," *Hall v. Burger King Corp.*, No. 89-0260-CIV-KEHOE, 1992 WL 372354, at *11 (S.D. Fla. Oct. 26, 1992). They have done so even where injunctive classes have been proposed alongside separate damages classes if the "primary intent" driving the action "is to recover damages for past purchases." *In re Flash Memory Antitrust Litig.*, No. C 07-0086 SBA, 2010 WL 2332081, at *7 (N.D. Cal. June 9, 2010); *see also In re Processed Egg Prods. Antitrust Litig.*, 321 F.R.D. 555, 558 (E.D. Pa. 2017) (observing that antitrust cases "at their core seek relief from economic harm" and declining to certify a (b)(2) class after denying certification to a separate (b)(3) class).

IV. CONCLUSION

Plaintiffs' Motion for Class Certification should be denied in its entirety.

Respectfully submitted,

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